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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,508	06/27/2005	Zeger Debyser	50304/072001	6752
21559	7590	05/31/2007		
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			EXAMINER BLUMEL, BENJAMIN P	
			ART UNIT	PAPER NUMBER
			1648	
			MAIL DATE	DELIVERY MODE
			05/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/529,508	Applicant(s) DEBYSER ET AL.	
	Examiner Benjamin P. Blumel	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-44 and 46-59 is/are pending in the application.
- 4a) Of the above claim(s) 30-43 and 51-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 44,46-50 and 57-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 March 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/28/05 and 3/5/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants are informed that further examination of this application will be conducted by Benjamin P. Blumel, contact information is stated below.

Election/Restrictions

Applicant's election without traverse of Group III in the reply filed on March 5, 2007 is acknowledged. Therefore, claims 44, 46-50 and 57-59 are examined in this Office action.

Claims 30-43 and 51-56 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on March 5, 2007.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on March 28, 2005 was filed. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

The information disclosure statement (IDS) submitted on March 5, 2007 was filed after the mailing date of the Election/Restriction on January 3, 2007. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

The drawings are objected to because figure 1 appears to contain 4 panels (A-D), however panel C is not label as such. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The abstract of the disclosure is objected to because the length exceeds the maximum length of 150 words. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 43, 45-50, 58 and 59 are rejected under 35 U.S.C. 102(e) as being anticipated by

Legrain et al. (US 2006/0034860 A1).

The claimed invention is drawn to a method of screening for molecule(s) with antiviral activity by exposing the protein LEDGF (Lens epithelium-derived growth factor)/P75 to said molecule(s) and observing the interaction between LEDGF and each molecule. The interaction is monitored with regard to the binding of the molecule(s) to the LEDGF while on HIV integrase (IN) or to the complex of LEDGF/P75 and IN. The claimed method also monitors the prevention or suppression of retroviral replication or integration by determining the modulation of nuclear transport of IN and monitoring the solubility of the IN and/or the step of crystallization of the IN. The claimed method involves introducing LEDGF/P75 protein and the molecule(s) into a cell culture and determining a change in the integration-interacting protein (INIP) cellular activity, which as defined in the specification is LEDGF/P75. In addition, the protein LEDGF is also known as P75, Inip76, DFS70 (*as stated in the instant specification*) and PSIP2 (*see Legrain et al.*).

In the instant case, Legrain et al. teach a method of screening for modulating compounds that inhibit or promote HIV protein-protein interactions. Specifically, Legrain et al. discuss that

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the interactions between HIV IN and cellular proteins that assist/promote viral integration/replication are ideal for identifying inhibitory compounds, thereby providing a potential anti-viral HIV therapy. Legrain et al. teach the use of a yeast two-hybrid system in identifying such modulating compounds, but they also state that their teachings are not limited to this method and that others well known in the art can be employed. Legrain et al. focused on 8 different proteins with regard to identifying HIV IN cellular partners, of which LEDGF, also known as PSIP2, was shown to localize onto a specific binding site of the IN enzyme. The importance of this association was proven by interfering with LEDGF expression by siRNA, which resulted in an 84% inhibition of HIV replication. Therefore, as Legrain et al. taught above, the identified complex can be screened for modulating compounds that inhibit such an association, thereby providing potential anti-HIV replication therapies. In addition, Legrain et al. discuss that LEDGF could assist in solubilizing the IN protein and also provide for a crystallized form of the IN protein. *See pages 1, 2, 3, 6, 9, 10, 19-23 and claims 19 and 20.*

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 57 is rejected under 35 U.S.C. 103(a) as being unpatentable over Legrain et al. as applied to claims 44, 45-50, 58 and 59 above, and further in view of Brodin et al. (Biochemistry, 2002).

The claimed invention as discussed above, also includes the step of determining the ability of test molecule(s) to suppress the promoting activity of strand transfer of HIV.

The teachings of Legrain et al. are discussed above, however, Legrain et al. do not specifically teach monitoring the suppression of strand transfer activity of HIV IN.

Brodin et al. teach the monitoring of HIV IN strand transfer after interring with the HIV-1 IN-DNA complex with different recombinant oligonucleotides. Brodin et al. monitored this step of IN involvement with a call because the ability of HIV to integrate its genome by strand transfer into the host cell's DNA ensures its replication and consistent presence within the host. This ability of HIV is one of the many reasons it continues to evade effective treatment regimes. Therefore, as stated above, Brodin et al. teach the employment of oligonucleotides with modified nucleotides that have antiviral properties. In particular, Brodin et al. observed significant inhibition of strand transfer (approx. 90% inhibition-Figure 1) when 6-oxycytosine oligonucleotides were utilized.

It would have been obvious to one of ordinary skill in the art to modify the methods taught by Legrain et al. in order to identify molecule(s) that interfere with the LEDGF/P75-HIV

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IN complex, thereby suppressing the strand transfer activity of HIV IN. One would have been motivated to do so, given the suggestion by Legrain et al. that the method be used to screen for HIV IN-cofactor inhibitory substances/molecules, thereby interfering with HIV activity. There would have been a reasonable expectation of success, given the knowledge that monitoring the strand transfer activity of HIV IN when potential inhibitors are tested can indicate effective anti-viral molecule(s), as taught by Brodin et al. Thus the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 58 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 58 recites the limitation "compound(s)" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Summary

No claims are allowed.


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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin P. Blumel whose telephone number is 571-272-4960. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


/Benjamin P Blumel/
Examiner
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